

### REMARKS

Claims 1, 2, and 7 stand rejected. Independent claim 1 has been amended herein to recite a method for determining if an individual has Autism, comprising the steps of: obtaining a stool sample from the individual; analyzing the stool sample to determine the presence or absence of one or more antigens associated with one or more different pathogens in the group consisting of *Helicobacter pylori*, *Cryptosporidium*, *Entamoeba histolytica*, *Giardia*, *Rotavirus*, *Camphylobacter*, and *Clostridium difficile*; and identifying the presence of the one or more different pathogens in the stool sample as a biomarker that indicates that the individual has Autism. Claim 7 has been amended to recite the method of claim 1, wherein at least one of the one or more different pathogens is *Helicobacter pylori*. Support for these amendments can be found in the originally filed claims and in Applicant's specification at, for example, page 12, line 22 to page 13, line 9; page 14, lines 16-20; page 15, lines 2-6; and Figure 4.

New claims 30-64 have been added. Support for these claims can be found in the originally filed claims and in Applicant's specification at, for example, page 9, lines 15-17; page 10, lines 5-11 and 19-21; page 12, line 22 to page 13, line 9; page 14, lines 16-20; page 15, lines 2-6; and Figure 4.

No new matter has been added by the amendments made herein. Applicant respectfully requests reconsideration and allowance of pending claims 1, 2, 7, and 30-64 in view of the above amendments and the following remarks.

### Petition to Revive Pursuant to 37 CFR § 1.137(b)

Applicant is responding herein to the Final Office Action dated July 27, 2004. Applicant has filed concurrently herewith a Petition to Revive pursuant to 37 CFR § 1.137(b), with associated Declarations in support of Applicant's Petition. Applicant respectfully requests revival and consideration of the present Request for Continued Examination and Submission. Applicant respectfully asserts that the entire delay in filing the required reply was unintentional.

### Rejections Under § 112

The Examiner rejected claims 1, 2, and 7 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Specifically, the Examiner stated that the specification is “enabling for diagnosing autism by detecting the presence of antigens from a plurality of pathogens listed, for example, in Figure 3 or on page 9 of the application,” but that the disclosure “does not reasonably provide enablement for method of such diagnosis by detecting antigens of a plurality of other pathogens.” Office Action at page 4.

Applicant respectfully traverses. Without acquiescing to the Examiner's rejection, and to further prosecution, Applicant has herein amended independent claim 1 to recite a method for determining if an individual has Autism, comprising the steps of: obtaining a stool sample from the individual; analyzing the stool sample to determine the presence or absence of one or more antigens associated with one or more different pathogens in the group consisting of *Helicobacter pylori*, *Cryptosporidium*, *Entamoeba histolytica*, *Giardia*, *Rotavirus*, *Camphylobacter*, and *Clostridium difficile*; and identifying the presence of the one or more different pathogens in the stool sample as a biomarker that indicates that the individual has Autism. Applicant has also amended claim 7 to recite wherein at least one of the one or more different pathogens is *Helicobacter pylori*. Applicant respectfully submits that the present claims are fully enabled and refers the Examiner to the specification at, for example, pages 12-13 and Figure 4, in which Applicant describes numerous pathogens present in the stool samples of individuals diagnosed as having autism. Applicant's disclosure identifies correlations between the presence of one or more of the pathogens recited in the present claims with the development of autism, and states that such correlations enable the specific diagnosis of autism. See, for example, page 13, lines 6-18. Applicant's disclosure also describes a stool immunoassay which can be used to determine the presence of one or more pathogens recited in the present claims based on the presence of certain antigens (*e.g.*, proteins associated with such pathogens). In light of these disclosures, a person having ordinary skill in the art would have understood how to make and use the presently claimed invention without undue experimentation. Accordingly, the present claims are fully enabled.

The Examiner also rejected claims 1, 2, and 7 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner stated that Applicant's specification "has not provided adequate written description for methods of diagnosing autism based on the presence of any combination of pathogens." Office Action at page 7.

Applicant respectfully disagrees. Compliance with the § 112 written description requirement requires sufficient information in the specification to show that the inventor possessed the invention at the time of that original disclosure. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) ("[T]he applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention."); *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000). The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. See *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976); *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971).

As described above, Applicant has herein amended independent claim 1 to recite a method for determining if an individual has Autism, comprising the steps of: obtaining a stool sample from the individual; analyzing the stool sample to determine the presence or absence of one or more antigens associated with one or more different pathogens in the group consisting of *Helicobacter pylori*, *Cryptosporidium*, *Entamoeba histolytica*, *Giardia*, *Rotavirus*, *Camphylobacter*, and *Clostridium difficile*; and identifying the presence of the one or more different pathogens in the stool sample as a biomarker that indicates that the individual has Autism. Applicant submits that the Examiner's initial burden with respect to the written description requirement has not been met with respect to the present claims, and that the present specification clearly satisfies the written description requirement.

Applicant respectfully submits that the specification provides more than sufficient support for the present claims and refers the Examiner to the specification at, for example, pages 12-13 and Figure 4, in which Applicant describes numerous pathogens present in the stool samples of individuals diagnosed as having autism. As described above, Applicant's disclosure also identifies correlations between the presence of one or more of the pathogens recited in the

present claims with the development of autism, and describes how such correlations can be used to diagnose autism. See, for example, page 13, lines 6-18. Applicant's disclosure also describes a stool immunoassay which can be used to determine the presence of one or more pathogens recited in the present claims based on the presence of certain antigens (*e.g.*, proteins associated with such pathogens). In light of these disclosures, a person having ordinary skill in the art would have understood that Applicant possessed the presently claimed invention at the time of that original disclosure.

In light of the above remarks and amendments, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

#### CONCLUSION

In light of the above, Applicant respectfully submits that claims 1, 2, 7, and 30-64 are in condition for allowance, which action is requested. The Examiner is invited to telephone the undersigned at 612-766-2006 if such further prosecution or expedite allowance of the present case.

Please apply \$468 for excess claims fees and \$1175 for petition for five month extension of time fees and other any charges or credits to deposit account 06-1050, referencing Attorney Docket No. 25324-0021001.

Respectfully submitted,

Date: November 13, 2009

/Teresa A. Lavoie/

Teresa A. Lavoie, Ph.D.  
Reg. No. 42,782

Fish & Richardson P.C.  
3200 RBC Plaza  
60 South Sixth Street  
Minneapolis, Minnesota 55402  
Telephone: (612) 335-5070  
Facsimile: (877) 769-7945